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ABSTRACT

Introduction Early infant diagnosis (EID) of HIV and timely initiation of antiretroviral therapy can significantly reduce morbidity and mortality among HIV-positive infants. Access to EID is limited in many low-income and middle-income settings, particularly those in which standard care involves dried blood spots (DBS) sent to centralised laboratories, such as in Papua New Guinea (PNG). We conducted a qualitative exploration of the feasibility and acceptability of implementing a point-of-care (POC) EID test (Xpert HIV-1 Qualitative assay) among health workers and key stakeholders working within the prevention of mother-to-child transmission of HIV (PMTCT) programme in PNG.

Methods This qualitative substudy was conducted as part of a pragmatic trial to investigate the effectiveness of the Xpert HIV-1 Qualitative test for EID in PNG and Myanmar. Semistructured interviews were undertaken with 5 health workers and 13 key informants to explore current services, experiences of EID testing, perspectives on the Xpert test and the feasibility of integrating and scaling up POC EID in PNG. Coding was undertaken using inductive and deductive approaches, drawing on existing acceptability and feasibility frameworks.

Results Health workers and key informants (N=18) felt EID at POC was feasible to implement and beneficial to HIV-exposed infants and their families, staff and the PMTCT programme more broadly. All study participants highlighted starting HIV-positive infants on treatment immediately as the main advantage of POC EID compared with standard care DBS testing. Health workers identified insufficient resources to follow up infants and caregivers and space constraints in hospitals as barriers to implementation. Participants emphasised the importance of adequate human resources, ongoing training and support, appropriate coordination and a sustainable supply of consumables to ensure effective scale-up of the test throughout PNG.

Conclusions Implementation of POC EID in a low HIV prevalence setting such as PNG is likely to be both feasible and beneficial with careful planning and adequate resources.

Trial registration number 12616000734460.

Strengths and limitations of this study

- Qualitative explorations of the feasibility and acceptability of new healthcare interventions can provide valuable information on barriers and enablers to implementation.
- This is the first study to explore the feasibility and acceptability of implementing a point-of-care early infant diagnostic test in a low HIV prevalence country in the Asia-Pacific region.We interviewed health workers and key staff within Papua New Guinea's HIV programme to explore their perspectives on the factors associated with successful implementation of the test within the context of a research project.
- The study was implemented in two clinics in the Highlands of Papua New Guinea and may, therefore, not be generalisable to other provinces or other countries in the region.

INTRODUCTION

Over 180 000 children aged less than 15 years are newly infected with HIV worldwide every year; the vast majority through perinatal transmission.[1] HIV in children progresses more rapidly than in adults, with up to 50% mortality in the first 2 years of life in the absence of antiretroviral therapy (ART).[2 3] Early infant diagnosis of HIV (EID) and timely ART initiation can significantly reduce morbidity and mortality among HIV-positive newborns and infants.[3] In most resource-constrained settings, EID testing is based on heel prick dried blood spot (DBS)

samples being sent to central laboratories for virological testing using specialised laboratory equipment and highly trained personnel.[4] This necessitates caregivers making a return visit to the clinics to receive test results, and may require multiple visits when results are not yet available. A review of EID in resource-constrained settings found significant disparities in the proportion of DBS test results returned to caregivers, with a range of 37%–90%, and with the time to results communication ranging from 9 days to 21 weeks.[5] It is estimated that only half of all HIV-exposed infants in low-income and middle-income countries receive an HIV test result within 2 months of birth as recommended by WHO guidelines.[6] Improvements in testing rates and reductions in turnaround times are crucial for reducing adverse outcomes for HIV-exposed infants.

With an estimated HIV prevalence of 0.8% in the adult population (15–49 years), Papua New Guinea (PNG) has the highest HIV prevalence in the Pacific region.[7–9] The PNG national HIV policy recommends HIV-exposed infants be tested at 6 weeks of age using DBS that are sent to the centralised laboratory in the capital, Port Moresby, for analysis.[10] According to UNAIDS data, 79% of pregnant women living with HIV receive antiretroviral medication for the prevention of mother-to-child transmission (PMTCT), and three-quarters of infants (75%) are tested for HIV within 2 months of birth.[9] PNG has limited transport and telecommunications infrastructure, very diverse geography and a predominantly rural population.[11–13] These factors contribute to logistical challenges with the transportation of DBS samples and communication of results leading to significant delays in the return of results to the clinic, to families and, where indicated, ART initiation.

According to WHO, a point-of-care (POC) test should be easy to use, accurate, affordable, equipment-free, robust, deliverable to end users and provide rapid results—ideally within 30 min.[14] One of the main benefits of POC testing is the availability of results and treatment during the same visit to a healthcare facility.[15] Despite taking 90 min to run, the Xpert HIV-1 Qualitative assay (Cepheid, Sunnyvale, California, USA) is widely considered to be a POC test given its ability to provide results on the same day as testing.[16] The molecular Xpert HIV-1 Qualitative test has proven to perform well both in the laboratory and in-field evaluations in high prevalence settings.[17–19] A recent observational study in eight African countries found that POC EID testing, including the Xpert HIV-1 Qualitative assay, significantly reduced the time to HIV test results communication and enabled earlier initiation of ART.[20] However, the availability of a POC test does not always translate to its widespread uptake. A number of factors can hinder the effective implementation of these technologies such as policies, user perspectives and health system constraints, including cost.[21] Examining the feasibility and acceptability of implementing a new healthcare intervention is one way to identify these barriers early and put strategies in place to address them.[22] While numerous studies have investigated the acceptability and feasibility of various POC tests including CD4 T cell tests and HIV rapid tests,[23–25] qualitative evidence on the feasibility and acceptability of implementing POC EID testing is lacking in both low prevalence settings and the Asia-Pacific region.

This paper evaluates the feasibility and acceptability of implementing the Xpert HIV-1 Qualitative test for EID in PNG, and explores the potential for scale-up throughout the country.

METHODS

This feasibility and acceptability assessment is one component of a cluster-randomised controlled stepped wedge trial of the effectiveness of the Xpert HIV-1 Qualitative test for EID on HIV-exposed infants in PNG and Myanmar. The overall study was undertaken in two hospitals in PNG, using both quantitative and qualitative methods.

Patient and public involvement statement

Patients and the public were not directly involved in the design, conduct, reporting or dissemination of the research. The results of the cluster-randomised trial and the qualitative substudies will be disseminated to local communities through workshops and written summaries of findings.

Study setting

PNG is the largest and most populated of the Pacific Island countries.[13] The health system faces a number of challenges including funding constraints, significant shortages of health workers, inconsistent availability of basic medication and supplies, and inadequately maintained health facilities.[12 26 27] It is within this context that PNG's PMTCT programme operates and in which this field trial was undertaken in two provincial hospitals: Mount Hagen Hospital (Western Highlands Province) and Goroka Base Hospital (Eastern Highlands Province). These public hospitals were chosen due to the relatively high number of pregnant women with HIV undergoing care and treatment at respective PMTCT clinics.

Overview of field trial

The field trial was implemented over 14 months with 6 months of follow-up of enrolled participants. Both study sites started in the control phase and moved into the intervention phase at different (randomly assigned) time points, following a transition month. During transition prior to the intervention phase, the GeneXpert platform was introduced into the facility and research nurses and other healthcare staff were trained on the technology. The machines were kept in the same room where patient consultations occurred and were primarily run by the research nurses. Standard care DBS testing was still undertaken during the intervention phase, and caregivers of enrolled infants were provided with both Xpert test and DBS results as they became available. The result of the Xpert test was used for

clinical decision making. Due to the stepped-wedge design of the study, Mt. Hagen implemented the intervention for 9 months and Goroka for 4 months. As part of the trial, qualitative data were collected from both caregivers with infants enrolled in the study (results presented elsewhere) as well as from health workers and key informants.

Qualitative data collection

Towards the end of field implementation, participants for this qualitative component were recruited from the two study sites in Goroka and Mt. Hagen as well as from the national capital Port Mores by, where the National Department of Health, Central Public Health Laboratory (CPHL) and other key non-government organisations (NGOs) are located. Interviews with health workers were undertaken either in the hospitals themselves or in a private office in the PNG Institute of Medical Research, adjacent to the clinic. With consent, key informant interviews took place in the offices of interviewees or appropriate rooms within their respective organisations in Port Moresby, Mt. Hagen or Goroka. The locations of all interviews ensured privacy and confidentiality were maintained. Qualitative data collection took place from January to April 2018, when both study sites were in their last months of field implementation.

Study participants

Five nurses across both sites were purposively recruited for in-depth interviews. This included one research nurse from each of the two sites who were responsible for study implementation, and three nurses working within PMTCT services at participating hospitals. Research nurses were hired specifically for this field trial and were employed at the PNG Institute of Medical Research and seconded to the respective clinics prior to implementation. Both research nurses had previously worked at their respective hospital, were familiar with the setting and the staff and were well trained in clinical care. In addition, 13 key informants were recruited: senior staff within the PMTCT programme in Goroka (n=1), Mt. Hagen (n=2) and Port Moresby (n=2); staff from CPHL where standard care EID testing is performed (n=2); national government representatives (n=3) and staff from international and local NGOs (n=3). The international NGO is involved in providing technical support and policy advice regarding health in PNG and globally; whereas the local NGO provides community-led support and advocacy for people living with HIV in PNG. Local study investigators purposively identified key informants to maximise representation across the PMTCT programme within PNG. An additional two key informants from Port Moresby were contacted and asked to take part in the study, however responses were not received.

Research team

The first author (YM) drafted the semistructured interview guides with comprehensive revision and modification by the senior author (AK-H) prior to finalisation. Interviews were undertaken by an experienced postgraduate female social scientist from the PNG Institute of Medical Research (MK), and who had no previous involvement in the implementation of the main study.

Design

Semistructured interviews with health workers explored current PMTCT services, experiences of standard care EID based on centralised DBS testing, involvement in study implementation including experiences with and perspectives on the Xpert HIV-1 Qualitative test for EID, acceptability of same-day HIV results, and the feasibility of integrating the test into routine clinical care. Interviews with key informants focused on their experiences with study implementation where applicable, the scope and quality of the current PMTCT programme, the perceived impact of POC EID on health services, and the feasibility of test scale-up throughout PNG.

A total of 18 interviews were conducted with the majority lasting between 30 and 90 min. Interviews were conducted either in English or Tok Pisin (both national languages in PNG), depending on the preference of the interviewee, and were digitally recorded with participants' consent.

Data analysis

All interviews were transcribed verbatim and, where necessary, translated into English. Each transcript was carefully reviewed by the interviewer to ensure the accuracy and consistency of transcription and translation. Transcripts were coded using both an inductive and deductive approach with NVivo V.11 qualitative data analysis Software (QSR International). The first author developed a coding framework following an initial reading of the data and using existing acceptability and feasibility frameworks from the published literature.[22 28 29] Following verification of the coding framework by the qualitative researcher who collected the data and the senior author, the first author systematically coded each transcript and analysed the data according to the frequency and content of codes and themes.

Ethical considerations

Written informed consent was obtained from each participant, and all interviews were digitally recorded with written consent from interviewees. All identifiable information was removed, and no names used to identify study participants. Electronic transcripts were stored on password-protected computers accessible only to members of the research team involved in the analysis.

RESULTS

Participant characteristics

A total of 18 participants were included in this qualitative inquiry—5 health workers and 13 key informants. An overview of study participants is presented in table 1. Both research nurses and most of the clinical staff were based at the study sites in Mt. Hagen and Goroka, while the majority of key informants involved in HIV policy and

Table 1 Overview of study participants by organisation, position type, location and sex

Organisation	Position type	No of participants by location (sex)			
		Mt. Hagen	Goroka	Port Moresby	Total
Healthcare workers					
PNG Institute of Medical Research	Research nurse	1 (F)	1 (F)		
Provincial Hospitals	Clinical nurse	1 (F)	2 (F)		
Subtotal		2	3		5
Key informants					
Provincial Hospitals	Clinical	1 (F)			
	Laboratory	1 (M)			
	Programmatic		1 (M)		
Port Moresby General Hospital	Clinical			1 (F)	
	Programmatic and clinical			1 (F)	
Central Public Health Laboratory	Laboratory			2 (M)	
National Department of Health	Programmatic and clinical	1 (F)		1 (M)	
National AIDS Council Secretariat	Programmatic and policy			1 (M)	
WHO	Programmatic and policy			1 (M)	
Local NGO	Community representative			2 (F, M)	
Subtotal		3	1	9	13
Total		5	4	9	18

F, female; M, male; NGO, non-government organisation; PNG, Papua New Guinea.

programming were based in Port Moresby. All five healthcare workers interviewed were female, and 7 of 13 key informants were male.

The main themes identified included challenges with current EID services and the consequent need for POC EID testing; the perceived impact of POC EID on quality of care for infants and caregivers, and the potential benefits for the PMTCT programme more broadly; barriers and facilitators to integration of the Xpert test into routine clinical care, including factors to be considered prior to scale-up of POC EID throughout the country.

Acceptability of POC EID testing

Perceived need for POC EID

POC EID testing was seen by both health workers and key informants as a potential way to overcome the existing challenges within the current EID programme. Health workers, laboratory staff and policy-makers in all sites noted the long turnaround time between DBS collection from HIV-exposed infants and the communication of results to facilities and families. Reasons for this delay included the absence of a current National Department of Health PMTCT programme coordinator since the previous year; the availability of only one Roche Amplicor HIV-1 Qualitative DNA assay for virological testing (V.1.5; Roche Molecular Systems, Branchburg, New Jersey, USA) in Port Moresby for testing samples for the entire country; the limited number of laboratory staff employed to run the machine for EID testing; and the lack of consistently available government funds to maintain testing. Inadequate communication channels between hospital and laboratory services also contributed to the delay in the return of results, with health workers describing telephoning and emailing CPHL but being unable to get through to the appropriate department, sometimes due to network failures. The lack of clear, consistent guidelines for results communication between the hospitals and CPHL further exacerbated delays and increased the perceived need for a POC EID.

Health workers and key informants described how, in some cases turnaround times of several months for EID results prevented HIV-infected infants from commencing ART in a timely manner. This was acknowledged as having profound implications for the health of HIV-exposed infants as well as the emotional well-being of caregivers.

> We lose a lot of cases (…) where we are sending samples to CPHL, and they wait for 6 months and sometimes they (infants) die. (Key informant, laboratory, Mt. Hagen)

> …they (HIV-infected women) don't want their children to become infected. So having to wait for that period, finding out whether (their baby is) positive or negative is very traumatizing. (Key informant, community, Port Moresby)

The delay in receiving infants' HIV results from the central laboratory was particularly challenging for health workers. Clinical staff described feeling 'frustrated',

'guilty' and 'ashamed' at not being able to provide results to caregivers returning to the hospitals.

> …when the same mother comes back I usually feel ashamed to talk (…). It is my job too so I would give excuses that the machine in Moresby is probably damaged or we didn't receive the email and they didn't send back (the results), and man, I would get cross for no good reason on here in front of the mothers. (Clinical nurse, Mt. Hagen)

These feelings negatively impacted on job satisfaction and reduced the perceived quality of care that could be provided. Some caregivers, they shared, would stop returning altogether if results were extensively delayed.

Perceived impact of POC EID on quality of care

Being able to commence HIV-infected infants on ART 'straight away' was identified by all study participants as the main advantage of POC EID testing, reducing the likelihood of child morbidity and mortality.

> …we saved four babies with the result of the (GeneXpert) machine. They are tolerating (ART) really well. (Research nurse, Mt. Hagen)

Another benefit of POC EID testing was a sense of job satisfaction at providing good quality care to caregivers and babies.

> For the mothers, they need to hear the results sooner, and we also want to hear the results sooner also for our jobs, we will feel motivated to work. (Clinical nurse, Mt. Hagen)

Research nurses reported a reduction in lost to follow-up of HIV-exposed infants and their caregivers due to the provision of same-day results. Hospital staff in the study sites stated that more caregivers were coming to the clinics for EID testing as a result of the availability of same-day results than would normally be expected with standard EID testing. Health workers felt that caregivers were more motivated to return to the clinic for appointments in order to find out if their child or children had HIV, and that the majority were willing to wait for 90 min to receive HIV test results.

> She (mother) doesn't want the baby to be infected like herself, so she made her time available, and she came on time. (Research nurse, Goroka)

Health workers acknowledged that not all caregivers were able to wait for 90 min, in addition to the time for sample collection and preparation. POC testing was not able to address competing priorities that made it difficult for caregivers to stay at the clinic. For example, the research nurse in Mt. Hagen reported that one mother of twins was unable to wait for the test results because her husband 'chased her away' from the clinic. Both twins were found to be HIV-positive, and while staff made every effort to contact the family, it was not until after one twin had died that the family returned to the health facility.

The research nurse in Mt. Hagen highlighted potential risks associated with same-day results for HIV-exposed infants. Having received an HIV-negative test result for their child, some mothers may want to stop any ongoing HIV exposure for the infant by discontinuing breast feeding, despite breast feeding being recommended in national and international guidelines.[10 30] This risk was heightened in infants receiving same-day results who are likely to be much younger than those using the standard care DBS test.

> …sometimes when they hear this result, when the baby is negative, they quickly want to put the baby on Lactogen (formula) because they know that, their baby is negative so they don't want to breast feed anymore. (Research nurse, Mt Hagen)

Another perceived risk was that mothers presenting for their infant's first EID test might not understand that further testing would still be required after cessation of breast feeding to definitively confirm the HIV status of the child, and may therefore not return to the clinic for further HIV testing. This was less of an issue with standard care testing as caregivers often brought their children back to the clinic multiple times to see if standard care results were available, whereas same-day testing reduced the need for multiple visits. Health workers felt that good quality counselling and provision of accurate information to caregivers immediately after provision of POC results could mitigate these risks.

Potential benefits for PMTCT programme

All interviewees believed the Xpert HIV-1 Qualitative test for EID would be beneficial for the PMTCT programme and the country overall. As one key informant described it, POC EID testing would bring the PMTCT programme to the 'next level'. Same-day EID results were seen as essential for improving maternal and child health services, and substantially impacting on the HIV epidemic in PNG.

> I think we're making progress against targets that we are setting, the 2030 targets of, zero new infection by 2030. So, if we're able to strengthen the PPTCT program, …the program will be matured, so that's a success. (Key informant, programmatic, Port Moresby)

By providing same-day results and reducing lost to follow-up, POC EID was seen as a way to improve reporting of paediatric HIV and enable better monitoring and evaluation of the effectiveness of the PMTCT programme in PNG. Laboratory staff from CPHL also appreciated the benefits of POC EID testing in health facilities, particularly in terms of reducing the strain on overburdened central laboratory services responsible for EID testing throughout the entire country.

Study participants highlighted the likely impact of POC testing on the efficiency of EID services, with benefits for patients, staff and the health system more broadly.

> I think it's going to have a great impact in terms of getting results within few hours and get them treated. So actually, we are saving lives. We identify in getting patients on treatment, and we are actually saving lives; that's impact. And I think this is a great benefit for the patients and it's for the country as well.
>
> (Key informant, laboratory, Mt. Hagen)

Key informants at the community, programmatic and policy levels identified the additional testing available through the GeneXpert platform, including tuberculosis and HIV viral load monitoring, as added benefits of the technology. This was perceived as an important facilitator for scale up and sustainability.

Feasibility of implementing POC EID

Human resources

Research nurses were recruited by the PNG Institute of Medical Research and colocated at both study sites to undertake study procedures and conduct POC EID testing during the intervention phase of the study. In some cases, they also relayed test results to caregivers. According to the health workers interviewed, the presence of these additional staff made implementation feasible at the study sites. Health workers acknowledged that without these research nurses, it would have been challenging to integrate POC EID into their existing workloads. This was especially true in Mt. Hagen, where the number of patients presenting for EID increased substantially during the study period, with participants hypothesising that this was due to the presence of the GeneXpert machine. Despite acknowledging the potential for an increased workload, the majority of health workers were willing to spend the time conducting POC EID due to its perceived importance for the quality of care provided.

In contrast, some health workers suggested that access to POC EID would reduce clinic staff workload by decreasing the amount of time spent transporting and following up on DBS samples sent for centralised laboratory testing in Port Moresby.

> This (Xpert HIV-1 Qualitative test) is making my job much easier (…). It's not like before where I used to go and send the samples to CPHL. If this study goes well, the thing (GeneXpert® machine) is already installed. I will not move around and waste my time out at the post office or wait for the result to come back. (Clinical nurse, Goroka)

Participants emphasised the importance of training and hiring an appropriate number of staff in facilities where POC EID services would be implemented. According to health workers, training on the GeneXpert machine and Xpert HIV-1 Qualitative test should be similar to that provided in this study with both theoretical and practical components, a focus on preparing the cartridges and running the test, the availability of written guidelines on testing procedures, and adequate supervision and support.

Key informants identified the importance of consistent implementation of standard operating procedures on all aspects of running the test as well as mechanisms for quality control and external quality assurance. Laboratory staff in particular described the need for adequate support, supervision and mentoring of clinical staff not familiar with laboratory testing procedures.

> We need to train nurses (…). They need to work very very closely with the lab persons or the experts in there. And the other challenge is that, because it's a machine that is being used in the lab, we try to take it out from the lab, put it in the clinic and my challenge is that the quality and the results being produced because there are likely to be mistakes being added. So there needs to be some sort of quality check on the reports that we produce. (Key informant, laboratory, Mt. Hagen)

Coordination

Key informants highlighted the need for appropriate coordination of the scale-up of any new technology throughout the country. Multiple participants mentioned the importance of the National Department of Health taking ownership of a national programme, especially with regard to sustainable funding and essential coordination for driving the scale-up as well as maintaining the quality of services.

Other key informants felt that decentralising the EID services would be more beneficial to the effectiveness of the programme, ensuring that someone was available at each hospital to address any unforeseen challenges.

Integration of POC EID into health services

While the majority of Xpert HIV-1 Qualitative test results were provided on the same day, health workers described instances of patients arriving late in the day and consequently having to return the next day for their results. Although no longer POC testing by definition, health workers agreed that next day results were still faster than standard care. The clinics attempted to maximise same-day results by prioritising caregivers bringing their children in for EID testing and commencing these tests immediately wherever feasible. The research nurses also identified the ability to store infant blood samples for up to 72 hours as an advantage of the test, making testing easier to integrate into routine clinical care. Some health workers also appreciated that the 90 min during which the Xpert HIV-1 Qualitative test was running could be used to undertake other clinical duties such as health education.

One particular challenge that the research team faced in implementing POC EID in the two study sites was following up caregivers who were unable to wait for same-day results and did not return to the clinic the following day. Caregivers were difficult to trace because no systems were in place at either study site for follow-up, research nurses did not have consistent access to a vehicle

for home visits, and many caregivers were not contactable by mobile phone.

> The communication system that was another challenge that I had…Sometimes when (caregivers) give their numbers to us, someone else is answering the phone and not this client. They lose their phones sometimes, and that's another challenge about follow-ups. (Research nurse, Mt. Hagen)

Infrastructure

Identifying an appropriate location for the GeneXpert machine within the clinics was important for implementing POC EID testing. Both study sites have a high patient load and limited space, and health workers highlighted the challenges of trying to fit the new technology into the clinic.

Ensuring a sustainable and consistent supply of test cartridges was also identified as an important aspect of integrating POC EID testing into routine clinical care. While both sites had sufficient numbers of cartridges throughout the study, maintaining the supply proved challenging at times as enrolment numbers increased unexpectedly in Mt. Hagen. The Alere PIMA machine was cited as an example of a technology that has not been sustainably scaled up in PNG, with sites currently lacking access to cartridges and therefore being unable to run POC CD4 tests. Ensuring the sustainability of POC EID testing was believed to require clear delegation of responsibilities for ordering cartridges and necessary supplies. Multiple key informants identified the cost of cartridges as a potential challenge to sustainability.

> We are happy for the scaling up to go rural, especially at the district level but the funding is a big problem for us. Who will now buy the GeneXpert Machine? Who will pay for the cartridges? (Key informant, programmatic, Goroka)

Maintenance of the GeneXpert machine was also identified as a potential challenge to scale-up, with key informants raising concerns about machines not being used if they broke down due to inadequate maintenance plans.

DISCUSSION

This is the first study to explore the feasibility and acceptability of implementing a POC EID test in a low HIV prevalence, lower-middle-income Asia-Pacific country. Health workers and key staff within the PMTCT programme found the Xpert HIV-1 Qualitative test for EID acceptable and feasible to implement within the context of a research project and potentially more broadly, and all participants believed that the test would reduce time to treatment initiation and improve the quality of care provided to HIV-exposed infants and their families. A nurse-led model of care combined with the presence of research nurses at the two study sites enabled immediate initiation of ART for infants found to be HIV-infected on the same day as testing. POC EID has been demonstrated to significantly reduce the time to provision of HIV test results and enable earlier ART initiation.[20] The potential benefits of scaling up POC EID are particularly important in a context like PNG where PMTCT services are constrained, and preventable transmission of HIV from mothers to their children occurs, although the cost-effectiveness in a low prevalence setting warrants further investigation.

According to study participants, the primary benefit of POC EID testing is the provision of same-day results and immediate initiation of treatment for HIV-positive infants. Research has clearly shown the importance of early treatment initiation for the health of HIV-exposed infants, with an up to 76% reduction in infant mortality.[2] POC EID has recently been shown to be effective in improving the turnaround time of results and enabling earlier ART initiation in high HIV prevalence settings.[20] While our study highlights the considerable potential of the Xpert HIV-1 Qualitative test to improve quality of care within the EID programme in PNG, a number of key strategies need to be in place within the PMTCT cascade to maximise impact.[5] For example, all pregnant women must have access to HIV testing and treatment, and mechanisms for efficient patient follow-up need to be established.[5]

Health workers interviewed in this study highlighted two potential challenges with the provision of same-day EID results. First, obtaining an HIV result early could conceivably impact on a caregiver's motivation to return to the clinic for final confirmatory testing after the cessation of breastfeeding. It is likely, however, that the benefits of finding out an infant's HIV status on the same day as testing outweigh the risks of potential lost to follow-up in the future, especially considering that caregivers may become lost to follow-up within standard EID programmes and consequently never receive a test result for their infant. A study looking at barriers to EID in Malawi found that one third of women living with HIV did not return for their child's HIV test results, primarily due to transportation challenges.[31] Promisingly, a recent qualitative inquiry in Lesotho looking at very early diagnosis of HIV in infants found that mothers and health workers did not believe that birth testing would impact on the likelihood of returning to health facilities for subsequent HIV testing.[32]

The second identified challenge with same-day testing was the potential cessation of breastfeeding by mothers whose infants were found to be HIV negative. In the context of lifelong ART for all adults living with HIV including pregnant women, WHO recommends exclusive breastfeeding for the first 6 months of life and continued breast feeding up to 2 years and beyond for all infants born to women living with HIV.[33] Particularly in a setting such as PNG with a high burden of childhood illness, early cessation of breast feeding could have significant consequences for infant and child morbidity and mortality.[34] In addition, a qualitative study in PNG found that front-line

health workers are not aware of best practice infant feeding guidelines within the context of HIV.[35] With wider scale-up of POC EID in PNG, monitoring the impact of same-day results on breastfeeding practices would be advisable. Further promotion of exclusive breastfeeding through individual and group counselling at antenatal and postnatal care by both health workers and peer counsellors would likely mitigate any detrimental impact of POC EID testing on breastfeeding rates.[36]

Within the context of a research project, health workers found implementation of POC EID to be feasible in the two study sites. The availability of additional staff members to perform the test was essential to ensure integration of the testing procedure into routine clinical care. Research nurses were also responsible for study-specific data collection, which would not be required once the test was scaled up outside of the research context. Performing the Xpert HIV-1 Qualitative test does have an impact on the workload of clinic staff, particularly as the test is more complex and takes longer to run than the average lateral flow POC device. A systematic review of the acceptability and feasibility of POC CD4 testing identified increased staff workload as an important operational challenge.[24] However, health workers involved in our project were very optimistic about the potential for integration of the test into routine practice, and many were willing to increase their own workload for the benefit of their patients. A recent study in South Africa found that health workers were willing and able to manage the additional workload associated with POC EID testing using the Alere q 1/2 Detect device, and concluded that POC EID testing was highly acceptable in a field setting.[37] Ensuring adequate staffing in clinics where POC EID is implemented will be crucial for sustainability, especially within a health system facing a chronic shortage of health workers and considerable resource constraints, as is the case in PNG.[12 27 38]

Study participants identified the importance of adequate human resources; ongoing training and support; a sustainable supply chain; sufficient space for the GeneXpert machine; and effective coordination and oversight to maximise the sustainability of POC EID in PNG. These components are similar to those highlighted in other feasibility studies of novel healthcare interventions, particularly in low-income and middle-income country settings. A lack of coordination of maternal and infant HIV services negatively impacted on EID outcomes in a study in Malawi[39] and a review of barriers to scale up of POC technologies also identified infrastructure, workflow, training and supply chain as important challenges.[21] Importantly, these key drivers of sustainability have been reported by health workers as significant challenges within the current PMTCT programme in PNG.[38]

Ensuring adequate resources to follow-up patients was identified in our study as an important component of sustainable scale-up of the Xpert HIV-1 Qualitative test. Tynan *et al*[38] also describe patient follow-up as a pervasive barrier to successful implementation of the PMTCT programme in PNG. It is, however, worth noting that the availability of POC EID testing is likely to reduce the need for active tracing of mother–infant pairs for results communication compared with standard care DBS testing.

This study has a number of limitations that impact on the interpretation of the findings. While the qualitative researcher facilitating the semistructured interviews was not part of the overall study team, she is a staff member of one of the organisations leading the project. Therefore, it is possible that social desirability bias could have resulted in a tendency towards a focus on the positive aspects of POC EID by participants. It is also possible that key informants who were contacted to take part in this qualitative inquiry but did not respond to these requests had a different opinion to those who were interviewed. Finally, the overall study was only implemented in two clinics in the Highlands of PNG and may therefore not be generalisable to other provinces. Obtaining the perspectives of key stakeholders in Port Moresby with considerable experience of the national EID programme helped to mitigate this risk.

CONCLUSIONS

The Xpert HIV-1 Qualitative test is acceptable and feasible to implement in a low prevalence, lower-middle-income country setting such as PNG within a research context and potentially more broadly, and will likely be beneficial to the national PMTCT programme. POC EID has the potential to reduce the time to initiation of life-saving treatment among HIV-infected infants in PNG. Ensuring the availability of sufficient human resources, sustainable funding and effective coordination are critical for successful implementation of POC EID in this setting.

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